

AFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
m 900 N

Refer to: CFN 1123258

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

May 8, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

Ms. Nancy Galli, President
Nancy's Homemade Fudge
Rt. 795, P.O. Box 860
Meadows of Dan, Virginia 24120

Dear Ms. Galli:

During an inspection of your facility conducted by the Food and Drug Administration (FDA) on April 18, 1997, deviations from the Good Manufacturing Practice Regulations (GMP) (Title 21, Code of Federal Regulations (CFR), Part 110) were documented with respect to your firm's candy processing operation. By virtue of these deviations, the products processed at your facility are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. At the conclusion of the inspection, you were presented with a Form FDA-483 listing these deviations.

The following is a list of the insanitary conditions observed by our investigator during the inspection:

1. Rodent activity observed on a pallet stored in the northwest corner of the warehouse, containing various food products, including 4 burlap bags of raw peanuts:
 - (a) 17 rodent excreta pellets on the top of 1 of 4 bags of raw peanuts
 - (b) 11 rodent excreta pellets on the top and corners of the second of 4 bags of raw peanuts
 - (c) 3 rodent excreta pellets on the inner edge of the third of 4 bags of raw peanuts. Additionally, this bag had an approximate one inch by one inch apparent rodent gnawed hole through the burlap and plastic liner.
 - (d) approximately 200-300 rodent excreta pellets and apparent urine stains on the cardboard pallet slip beneath the food products on the referenced pallet

Ms. Nancy Galli

Page 2

May 8, 1997

2. Rodent activity observed in the warehouse:
 - (a) approximately 50 rodent excreta pellets observed on the floor in the northwest corner
 - (b) 2 approximate one inch apparent rodent gnawed holes were observed in the insulation at the floor/wall juncture in the northwest corner
3. An approximate two inch hole exiting to the outside of the building at the base of the north wall.

Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated, in accordance with 21 CFR 110.35(a). No pests shall be allowed in any area of a food plant, in accordance with 21 CFR 110.35(c). 21 CFR 110.35(c) further requires that effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests.

We acknowledge that your firm voluntarily destroyed the bag of raw peanuts containing the apparent rodent gnawed hole. However, it is your responsibility to have an effective, ongoing sanitation program for your facility which eliminates the insanitary conditions that we have observed, and which will assure continuing adherence to the requirements of the GMP regulations.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent recurrence of similar violations.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, Suite 424, 10710 Midlothian Turnpike, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer.

Sincerely,

William M. Ment

William M. Ment

Acting Director, Baltimore District